

§ 184.1973

21 CFR Ch. I (4–1–98 Edition)

(1) Crystalline vitamin D₂ (C₂₈H₄₄O, CAS Reg. No. 50–14–6), also known as ergocalciferol, is the chemical 9,10-seco(5Z,7E,22E)-5,7,10(19),22-ergostatetraen-3-ol. The ingredient is produced by ultraviolet irradiation of ergosterol isolated from yeast and related fungi and is purified by crystallization.

(2) Crystalline vitamin D₃ (C₂₇H₄₄O, CAS Reg. No. 67–97–0), also known as cholecalciferol, is the chemical 9,10-seco(5Z,7E,)-5,7,10(19)-cholestatrien-3-ol. Vitamin D₃ occurs in, and is isolated from, fish liver oils. It is also manufactured by ultraviolet irradiation of 7-dehydrocholesterol produced from cholesterol. It is purified by crystallization. Vitamin D₃ is the vitamin D form that is produced endogenously in humans through sunlight activation of 7-dehydrocholesterol in the skin.

(3) Vitamin D₂ resin and vitamin D₃ resin are the concentrated forms of irradiated ergosterol (D₂) and irradiated 7-dehydrocholesterol (D₃) that are separated from the reacting materials in paragraphs (a) (1) and (2) of this section. The resulting products are sold as food sources of vitamin D without further purification.

(b) Vitamin D₂ and vitamin D₃ as crystals meet the specifications of the Food Chemicals Codex, 3d Ed. (1981), pp. 344 and 345, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408. FDA is developing food-grade specifications for vitamin D₂ resin and vitamin D₃ resin in cooperation with the National Academy of Sciences. In the interim, these resins must be of a purity suitable for their intended use.

(c)(1) In accordance with § 184.1(b)(2), the ingredients are used in food as the sole source of added vitamin D only within the following specific limitations:

Category of food	Maximum levels in food (as served)	Functional use
Breakfast cereals, § 170.3(n)(4) of this chapter.	350 (IU/100 grams).	Nutrient supplement, § 170.3(o)(20) of this chapter.

Category of food	Maximum levels in food (as served)	Functional use
Grain products and pastas, § 170.3(n)(23) of this chapter.	90 (IU/100 grams)	Do.
Milk, § 170.3(n)(30) of this chapter.	42 (IU/100 grams)	Do.
Milk products, § 170.3(n)(31) of this chapter.	89 (IU/100 grams)	Do.

(2) Vitamin D may be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) or with regulations promulgated under section 412(a)(2) of the act.

(3) Vitamin D may be used in margarine in accordance with § 166.110 of this chapter.

(d) Prior sanctions for these ingredients different from the uses established in this section do not exist or have been waived.

[50 FR 30152, July 24, 1985]

§ 184.1973 Beeswax (yellow and white).

(a) Beeswax (CAS Reg. No. 8012–89–3) is a secretory product of honey bees used as a structural material in honeycombs. Beeswax is prepared from honeycombs after removal of the honey by draining or centrifuging. The combs are melted in hot water or steam or with solar heat, and strained. The wax is refined by melting in hot water to which sulfuric acid or alkali may be added to extract impurities. The resulting wax is referred to as yellow beeswax. White beeswax is produced by bleaching the constituent pigments of yellow beeswax with peroxides, or preferably it is bleached by sun light.

(b) The ingredient meets the specifications of the “Food Chemicals Codex,” 3d Ed. (1981), pp. 34–35, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(c) The ingredient is used as a flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter, as a lubricant as defined in § 170.3(o)(18) of this chapter, and as a surface-finishing

agent as defined in §170.3(o)(30) of this chapter.

(d) The ingredient is used in food, in accordance with §184.1(b)(1) of this chapter, at levels not to exceed good manufacturing practice. Current good manufacturing practice results in a maximum level, as served, of: 0.065 percent for chewing gum as defined in §170.3(n)(6) of this chapter; 0.005 percent for confections and frostings as defined in §170.3(n)(9) of this chapter; 0.04 percent for hard candy as defined in §170.3(n)(25) of this chapter; 0.1 percent for soft candy as defined in §170.3(n)(38) of this chapter; and 0.002 percent or less for all other food categories.

[43 FR 14644, Apr. 7, 1978, as amended at 49 FR 5613, Feb. 14, 1984; 50 FR 49536, Dec. 3, 1985]

§ 184.1976 Candelilla wax.

(a) Candelilla wax (CAS Reg. No. 8006-44-8) is obtained from the candelilla plant. It is a hard, yellowish-brown, opaque-to-translucent wax. Candelilla wax is prepared by immersing the plants in boiling water containing sulfuric acid and skimming off the wax that rises to the surface. It is composed of about 50 percent hydrocarbons with smaller amounts of esters and free acids.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 67, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a lubricant as defined in §170.3(o)(18) of this chapter and as a surface-finishing agent as defined in §170.3(o)(30) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: in chewing gum as defined in §170.3(n)(6) of this chapter and in hard candy as defined in §170.3(n)(25) of this chapter.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 51617, Nov. 10, 1983]

§ 184.1978 Carnauba wax.

(a) Carnauba wax (CAS Reg. No. 008-015-869) is obtained from the leaves and buds of the Brazilian wax palm *Copernicia cerifera* Martius. The wax is hard, brittle, sparingly soluble in cold organic solvents and insoluble in water. It is marketed in five grades designated No. 1 through No. 5. Grades No. 4 and No. 5 represent the bulk of the commercial trade volume. These commercial grades consist chiefly of C₂₄ to C₃₂ normal saturated monofunctional fatty acids and normal saturated monofunctional primary alcohols.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 73, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an anticaking agent as defined in §170.3(o)(1) of this chapter; as a formulation aid as defined in §170.3(o)(14) of this chapter; as a lubricant and release agent as defined in §170.3(o)(18) of this chapter; and as a surface-finishing agent as defined in §170.3(o)(30) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: